

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO: WAVE 1 CASES ATTACHED ON EXHIBIT A</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**REPLY IN SUPPORT OF PLAINTIFFS' MOTION  
TO EXCLUDE THE OPINIONS OF DR. SHELBY THAMES**

In further support of their Motion to exclude certain opinions and testimony of Defendants' expert, Dr. Shelby Thames ("Dr. Thames"), Plaintiffs state as follows:

**INTRODUCTION**

Dr. Shelby Thames is eager to defend Ethicon's Prolene material in these cases, but without reliable scientific support, his opinions cannot be allowed at trial. Ethicon's response to Plaintiffs' Motion provides no basis for Dr. Thames to testify that Prolene does not oxidize inside the body, nor is there any basis for him to tell any jury that Prolene does not lose molecular weight after implantation—as such, these opinions should be excluded.

Because Ethicon's response admits that the "dog study" did record Prolene's oxidation *in vivo*, and that it showed changes in molecular weight after implantation, the only Prolene-specific support Dr. Thames has for his oxidation opinions is the testing that he performed on explanted meshes. But that testing, itself, would have destroyed any evidence of oxidation that existed on Plaintiffs' meshes. Likewise, this same testing was the only basis of his opinions regarding the presence of translucent flakes and extrusion lines on explanted meshes. But he failed to use a control to determine how the various steps of his cleaning protocol would react to

human tissue and to any oxidized Prolene that existed on those explanted samples—rendering his oxidation and testing-based opinions without even the most basic support.

Additionally, Ethicon’s response attempts to bolster Dr. Thames’ “toughness” opinions by pointing to literature on the subject, but those explanations do not add up—and one needs only to look at Dr. Thames’ report to confirm that the underlying data was never collected in the dog study. Similarly, Ethicon attempts to augment Dr. Thames’ case-specific testing by including an affidavit from him explaining how the Proteinase-K used in his cleaning protocol did not destroy evidence of mesh oxidation. But Dr. Thames should have acted to protect evidence of oxidation on those meshes before he cleaned them—and—he should have explained his opinions about the chemistry involved in his report. Moreover, these two attempts to reinforce Dr. Thames’ report should be stricken—he was required to submit all of his opinions in his expert report and he did not.

Plaintiffs challenged Dr. Thames’ opinions and cleaning methodology because they are unscientific and unreliable. By his own admission, Dr. Thames needs to be 1,000% certain that there is oxidation taking place on Ethicon’s Prolene and this is an impossible standard.<sup>1</sup> This kind of zealousness is what allows Dr. Thames to apparently *believe* his opinions in these cases, but since it is just him who *believes* these things—without support from the scientific literature or community—they must be excluded from trial.

### **ARGUMENT**

The peer-reviewed literature does not support Dr. Thames’ opinions on Prolene’s oxidation inside the human body—and, in fact, it says the opposite happens.<sup>2</sup> Furthermore, Dr.

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<sup>1</sup> Ex. I to Motion, Thames Dep. at 45:747:10.

<sup>2</sup> Ex. 1, attached hereto, Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of

Thames' opinions about Prolene's oxidation, degradation, molecular weight and toughness are all focused on the data collected from Ethicon's internal dog study.<sup>3</sup> These opinions attempt to exist in a vacuum, and do not represent the kind of scientifically sound opinion testimony that should be heard by a jury.

**1. Ethicon admits that there were changes in molecular weight in the dog study.**

Ethicon admits that there were, in fact, changes in molecular weight found in Ethicon's internal "dog study"—Dr. Thames just does not believe them to be meaningful.<sup>4</sup> For that reason alone, Dr. Thames should be prevented from telling any jury that the dog study found *no* changes in molecular weight or that Prolene does not lose molecular weight when implanted in humans. Moreover, the results from the dog study are not the only evidence that Prolene oxidizes, degrades and loses molecular weight. There were, in fact, many internal examinations into Prolene's oxidation. Dr. Thames just disagrees with all of their findings that oxidation is happening.<sup>5</sup>

**2. Dr. Thames' Prolene oxidation opinions exist only in a vacuum—and ignore other reliable science.**

Ethicon's internal dog study was only one of Ethicon's decade-long Prolene oxidation studies—not its only study. The dog study's oxidation and tensile findings do not address or negate any of the previous studies conducted internally.<sup>6</sup> Prolene oxidizes, embrittles and loses molecular weight after implantation in the human body—Ethicon's own scientists have proven these facts—particularly in regards to the surface of the material. And while Dr. Thames' report

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Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) 199-206.

<sup>3</sup> Ex. C to Motion, Thames report, generally.

<sup>4</sup> Def's Brief at 8.

<sup>5</sup> Ex. C to Motion, Thames report at 31-38.

<sup>6</sup> Ex. D to Motion, ETH.MESH.05453719.

finds fault with a decade's worth of internal oxidation studies, he is able to focus all of his oxidation opinions on some tensile testing done on 6 sutures explanted on year 7 of the dog study.<sup>7</sup> To be clear, Dr. Thames disagrees with all of the internal conclusions of Prolene oxidation and degradation, including those from the dog study, but he does not address the tensile testing that was performed in years 1 and 2—and instead, he focuses only on year 7.<sup>8</sup>

Dr. Thames "belief" that Prolene does not degrade cannot be "bolstered" by the tensile data collected in the seventh year of this study if he is going to discredit all of its findings.<sup>9</sup> There were only 6 sutures tested and all of those sutures might have been extruded at the same time, from the same batch of Prolene—that level of detail is just not available—meaning that no statistical significance can be garnered from this tensile data. Dr. Thames has the burden of providing reliable opinion testimony—arguing that this year 7 data from 6 sutures proves that Prolene does not oxidize cannot be considered reliable and it should be excluded.

**3. Dr. Thames' report does not contain any information about how he formed his opinion that the data from year seven of dog study showed an increased toughness.**

Dr. Thames' report only states that he "extrapolated" the data needed to form his toughness opinions, but the support for that statement is not cited in his report, nor is there any statement about toughness made in the dog study itself.<sup>10</sup> And while Ethicon's response does try to strengthen Dr. Thames' report by adding citations and explanations that are not in Dr. Thames' report or reliance materials,<sup>11</sup> the analysis of his opinions should rest on what was

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<sup>7</sup> Ex. C to Motion, Thames report at 31-38.

<sup>8</sup> Ex. C to Motion, Thames report at 6.

<sup>9</sup> Ex. C to Motion, Thames report at 6.

<sup>10</sup> Ex. C to Motion, Thames report at 6-9.

<sup>11</sup> Gere & S. Timoshenko, *Mechanics of Materials*, 14 (1997) does not appear in Dr. Thames reliance; see also Def's Brief at 9-12.

recorded in the actual study and what is in Dr. Thames' report—and neither of those things explain how any indication of toughness can be deciphered from the data collected.

As an initial matter, Dr. Thames bases his toughness opinion on the assertion that the dog study's oxidation findings were wrong, and that it reported *no* changes in molecular weight.

Q. Let me ask this question, then. In the dog study, that was a study done by Burkley.

A. Yes, sir.

Q. B-U-R-K-L-E-Y. Did Dr. Burkley conclude that oxidative degradation took place?

A. He indicated that there might be some oxidative degradation, and he was wrong. Because if there had been, you would not see a [stress strain] curve like this. It's impossible to have oxidative degradation and have that curve of physical properties and no loss in molecular weight.

Q. Okay.

A. They go together. It's like being married and having your first child. You know, carbonyl group formation, loss in molecular weight and physical properties, they all go together.<sup>12</sup>

To begin with, and as stated above, Ethicon's response admits that there were changes in molecular weight reported in its internal dog study, so Dr. Thames can no longer hold that opinion at trial. Secondly, his "toughness" opinion cannot negate all of the internal conclusions, including those from the dog study, that Prolene oxidizes, degrades, and loses molecular weight inside the body.

Yet Ethicon argues "[t]he dog study does indeed include recorded stress-strain data including modulus, breaking strength (or, "stress"), and elongation (or, "strain"), which were generated during tensile testing of pristine and explanted sutures."<sup>13</sup> But those values only represent how far the suture elongated and then broke under stress—the supposed stress/strain graph that Dr. Thames plotted has only this one breakage measurement for each explanted suture and that is not how a stress/strain curve is established—which was the whole point of Figure 5 in

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<sup>12</sup> Ex. I to Motion, Thames Dep. at 135:21-136:12

<sup>13</sup> Def's Brief at 9-12.

Dr. Thames' report.<sup>14</sup> This scientific deficiency did not go unnoticed—Ethicon dedicates three pages in its response brief to explaining how Dr. Thames “extrapolated” his findings of toughness—but that explanation is not coming from Dr. Thames or his report.<sup>15</sup> It is coming from Ethicon, and from citations that do not appear in Dr. Thames' reliance materials.<sup>16</sup>

The data Dr. Thames focuses on from this internal study tells us this: that in one experiment—and after 7 years of implantation in dogs—6 of Ethicon's Prolene sutures showed an increased breaking strength and elongation. But even then, those conclusions are not provided with a statistical validity—we don't know if those sutures were all extruded at the same time or how long they had been sitting on a shelf before they were implanted. And as Dr. Thames states in his report “at least 5 tests are required for statistical validity”<sup>17</sup>—he simply does not have enough information to generate any opinions regarding toughness with any kind of scientific certainty. The dog study tells us almost nothing about Prolene's tensile behavior, and it certainly does not tell us anything about an increased toughness, which is an opinion that just cannot be supported here.

Dr. Thames wants to testify that Prolene's toughness is being improved over time inside the human body, but he only has 6 sutures from year 7 of a study on dogs to support that opinion—and—Dr. Thames does not explain how he extrapolated his conclusions nor does he have the proper materials in his reliance to support his opinion. This is not scientifically reliable opinion evidence that should be shared with a jury. And even if Dr. Thames could provide

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<sup>14</sup> Ex. C to Motion, Thames report at 7.

<sup>15</sup> *Id.*

<sup>16</sup> *Mechanics of Materials*, 14 (1997) does not appear in Dr. Thames reliance; *see also* Def's Brief at 9-12.

<sup>17</sup> Ex. C to Motion, Thames report at 58.

scientific support for his opinion, Dr. Thames did not explain it in his report, and it is therefore unclear how he ever came to hold this opinion.

**4. Dr. Thames’ opinions on extrusion lines and translucent flakes are still unsupported.**

There is nothing in the peer-reviewed literature to support Dr. Thames’ opinions on the presence of extrusion lines and translucent flakes on explanted materials—he came to these conclusions on his own and they are *ipse dixit*. Ethicon argues that his opinions are supported by “using a scientifically sound and repeatable methodology,” but this misses the point.<sup>18</sup> This Court previously allowed Dr. Spiegelberg to testify about the presence of black specs in the Boston Scientific litigation using a similarly non-peer-reviewed method to examine pristine mesh—holding that the Plaintiffs’ complaints were more like grounds for cross-examination than exclusion.<sup>19</sup> Here, however, Dr. Thames’ opinions on these two issues are the tainted result of employing a cleaning protocol that is untested and unexplained. There is simply no way to know the affect that Dr. Thames’ protocol had on the meshes he examined—and he should not be allowed to testify about any conclusions that he drew from this tainted and unscientific protocol.

**5. Dr. Thames’ cleaning protocol taints everything associated with his examination of explanted mesh and his opinions related to it should be excluded entirely.**

Dr. Thames is a zealous defender of Ethicon’s Prolene. He disagrees with a decade’s worth of internal scientific oxidation research, the published peer-reviewed literature, and the principles of polymer science in order to offer his opinions in these cases. His *belief* that Prolene

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<sup>18</sup> Def’s Brief at 13.

<sup>19</sup> *Frankum v. Boston Sci. Corp.*, No. 2:12-cv-00904 2015 U.S. Dist. LEXIS 57251, at \*66-67 (S.D. W. Va. May 1, 2015).

is special is based on his personal requirement that he be 1,000% certain that oxidation is taking place *in vivo* on Ethicon's Prolene.<sup>20</sup>

It is this unwavering *belief* that led Dr. Thames to utilize the cleaning protocol he created to examine Plaintiffs' meshes. First, he used Proteinase-K, which he explained would remove any carbonyls that were present on the explanted mesh, but Dr. Thames also explained that carbonyls would be the very evidence you would find if you did, in fact, have oxidation on explanted mesh.<sup>21</sup> To someone who insists that it is not possible for Prolene to oxidize, this may seem reasonable. And someone with that sort of tunnel-vision may also believe it is not necessary to run a control of oxidized Prolene (or any polypropylene) through his newly created cleaning protocol. To someone using the scientific method to search for the truth, however, all of this is entirely unreasonable.

Ethicon's response includes an affidavit from Dr. Thames stating new opinions and information that were not disclosed in his expert report<sup>22</sup>—as such, it should be stricken and not be considered part of Dr. Thames' expert report. However, even if these opinions are not stricken, his cleaning-protocol opinions should still be excluded.

Ethicon argues that Plaintiffs' misunderstand the science underlying Dr. Thames cleaning protocol, but this is not the case. Simply put, even if one assumes, *arguendo*, that Proteinase-K only removes carbonyls associated with protein and it will not react with any oxidized Prolene that exists underneath, Dr. Thames has still not accounted for how the products of that protein-only reaction will or will not affect oxidized Prolene. And he has also not tested how the rest of

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<sup>20</sup> Ex. C to Motion, Thames general depo at 45:747:10.

<sup>21</sup> Ex. I to Motion, Dr. Thames Dep. at 61:16-62:9; 46:12-48:19.

<sup>22</sup> Def's Brief at 14-17.



his cleaning protocol would have affected that same oxidized Prolene. A control was *necessary* under these circumstances and none was performed.

Dr. Thames' cleaning protocol calls for up to 25 steps to be performed on the meshes he examined.<sup>23</sup> Those additional steps include sonication, water, heat and bleach—all of which could have destroyed evidence of oxidation, assuming that the Proteinase-K had no effect. But Dr. Thames did not determine what effect, if any, his cleaning protocol has on oxidized Prolene. He assumed there would be none. As such, Dr. Thames' cleaning protocol and all opinions associated with it should be excluded.

### **CONCLUSION**

For the foregoing reasons, Dr. Thames should be limited in what he can testify about in these Wave 1 cases. No jury should ever hear any evidence that is unreliable—and the *ipse dixit* and factually unsupported statements by Dr. Thames complained about in Plaintiffs' Motion should be precluded. In addition, he has no basis to offer any case-specific opinions because his cleaning protocol likely destroyed whatever evidence of oxidation was originally on the meshes that he examined. Plaintiffs respectfully request their Motion be granted.

Dated: May 16, 2016

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<sup>23</sup> Ex. C to Motion, Thames report at 99-102.

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace

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